

# Notice of Allowability

Application No.

10/661,242

Examiner

Jennifer Dunston

Applicant(s)

LIEW ET AL.

Art Unit

1636

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to communication(s) filed 10/9/2007.
2. ☒ The allowed claim(s) is/are 37.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

- |  |   |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application                     |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date _____    | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance             |
|  | 9. <input type="checkbox"/> Other _____   |

### EXAMINER'S AMENDMENT

Receipt is acknowledged of an amendment, filed 10/9/2007, in which the specification was amended to include the information contained within the drawings as tables within the specification and to amend the specification to refer to the tables rather than the drawings. The amendment, filed 10/9/2007, has been ENTERED.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

The title has been changed to the following:

Diagnosis of mild osteoarthritis by determination of TNFAIP6 and TGFBI RNA levels

The drawings, filed 9/12/2003, have been deleted.

In the specification:

At the page 16, line 26, the word "Genbank" has been deleted and has been replaced therefore with the word "GENBANK".

At page 17, line 2, the word "Genbank" has been deleted and has been replaced therefore with the word "GENBANK".

At page 31, line 19, the phrase "Texas Red" has been deleted and has been replaced therefore with the phrase "TEXAS RED".

At page 31, line 2, the phrase "Cyanine 3 (Cy3) and Cyanine 5 (Cy5)" has been deleted and has been replaced therefore with the phrase "Cyanine 3 (CY3) and Cyanine 5 (CY5)".

At page 51, line 20, the word "pBluescript" has been deleted and has been replaced therefore with the word "PBLUESCRIPT".

At page 59, line 3, the word "Genbank" has been deleted and has been replaced therefore with the word "GENBANK".

At page 60, line 26, the word "Genbank" has been deleted and has been replaced therefore with the word "GENBANK".

At page 61, line 18, the word "Genbank" has been deleted and has been replaced therefore with the word "GENBANK".

At page 76, line 7, the phrase "Cy3 or Cy5" has been deleted and has been replaced therefore with the phrase "CY3 or CY5".

At page 80, line 15, the phrase "texas red" has been deleted and has been replaced therefore with the phrase "TEXAS RED".

At page 81, line 17, the word "Cy5" has been deleted and has been replaced therefore with the word "CY5".

At page 81, line 18, the word "Cy3" has been deleted and has been replaced therefore with the word "CY3".

At page 84, line 11, the phrase "Cy3 and Cy5" has been deleted and has been replaced therefore with the phrase "CY3 and CY5".

At page 84, line 24, the phrase "Cy5 to Cy3" has been deleted and has been replaced therefore with the phrase "CY5 to CY3".

At page 84, line 26, the phrase "Cy5 versus Cy3" has been deleted and has been replaced therefore with the phrase "CY5 versus CY3".

At page 93, line 12, the word "Genbank" has been deleted and has been replaced therefore with the word "GENBANK".

At page 95, line 1, the word "Cy3" has been deleted and has been replaced therefore with the word "CY3".

At page 95, line 2, the word "Cy5" has been deleted and has been replaced therefore with the word "CY5".

At page 95, line 10, the phrase "Cy3 and Cy5" has been deleted and has been replaced therefore with the phrase "CY3 and CY5".

At page 95, line 11, the phrase "Cy3 and Cy5" has been deleted and has been replaced therefore with the phrase "CY3 and CY5".

At page 97, line 11, the phrase "Cy3 or Cy5" has been deleted and has been replaced therefore with the phrase "CY3 or CY5".

At page 98, line 4, the phrase "Cy3 or Cy5" has been deleted and has been replaced therefore with the phrase "CY3 or CY5".

At page 99, line 8, the phrase "Cy3 and CyS" has been deleted and has been replaced therefore with the phrase "CY3 and CY5".

At page 99, line 11, the phrase "Cy3 and Cy5" has been deleted and has been replaced therefore with the phrase "CY3 and CY5".

At Table 1, line 1, the word "Genbank" has been deleted and has been replaced therefore with the word "GENBANK".

At Table 2, line 2, the word "Genbank" has been deleted and has been replaced therefore with the word "GENBANK".

At Table 3, line 2, the word "Genbank" has been deleted and has been replaced therefore with the word "GENBANK".

At Table 4, line 2, the word "Genbank" has been deleted and has been replaced therefore with the word "GENBANK".

At Table 5, line 1, the word "Genbank" has been deleted and has been replaced therefore with the word "GENBANK".

At Table 6a, line 2, the word "Genbank" has been deleted and has been replaced therefore with the word "GENBANK".

At Table 6b, line 1, the word "Genbank" has been deleted and has been replaced therefore with the word "GENBANK".

At Table 6c, line 1, the word "Genbank" has been deleted and has been replaced therefore with the word "GENBANK".

At Table 6d, line 1, the word "Genbank" has been deleted and has been replaced therefore with the word "GENBANK".

At Table 7a, line 2, the word "Genbank" has been deleted and has been replaced therefore with the word "GENBANK".

At Table 7b, line 2, the word "Genbank" has been deleted and has been replaced therefore with the word "GENBANK".

In the claims:

Claim 37. (Currently amended) A method of diagnosing mild osteoarthritis in a human test individual, said method comprising:

for each gene of the set of genes consisting of TNFAIP6 and TGFBI,

(a) determining the level of expression of RNA encoded by said gene in a cartilage sample of said individual; and

(b) comparing said level with the level of expression of RNA encoded by said gene in control cartilage samples, wherein said control samples are from individuals who have been diagnosed as not having osteoarthritis;

whereby ~~a difference between~~ an increase in said level of step (a) ~~and relative to~~ said level of expression of said RNA in said control samples is indicative of mild osteoarthritis.

Claim 38. (Canceled)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

Application/Control Number:  
10/661,242  
Art Unit: 1636

Page 7

system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Dunston  
Examiner  
Art Unit 1636

/JD/

/Daniel M. Sullivan/  
Primary Examiner  
Art Unit 1636